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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,152	11/16/2001	Stephanie Aquin	MBX 041	3848
23579	7590	01/13/2005		
PATREA L. PABST PABST PATENT GROUP LLP 400 COLONY SQUARE SUITE 1200 ATLANTA, GA 30361			EXAMINER MCELWAIN, ELIZABETH F	
			ART UNIT 1638	PAPER NUMBER

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/991,152

Applicant(s)

AQUIN ET AL.

Examiner

Elizabeth F. McElwain

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 29 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,7-12,16-19,23-26 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,13-15 and 20-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/15/02.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group II, claims 2, 3, 6, 14, 15, 21 and 22, and linking claims 1, 13 and 20 in the reply filed on October 25, 2004 is acknowledged. The traversal is on the ground(s) that in view of the amendment of the claims that the first seventeen groups are all drawn to the discovery of a single enzyme required to produce polyhydroxyalkanoates of predominantly medium chain length, that Groups I-XVII should be examined together. This is not found persuasive because the particulars of each of the other groups are not required by Group II, and therefore, would require additional search and would be an undue burden for search and examination.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-3, 6, 13-15 and 20-22 are examined on the merits.

Claims 4, 5, 7-12, 16-19, 23-26 and 29 are withdrawn.

Claims 27 and 28 are cancelled.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6, 13-15 and 20-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to bacteria or plants that produce PHA that are transformed with a gene encoding an enzyme having the catalytic activity of 3-hydroxyacyl-ACP thioesterase so that medium chain length PHA accumulates, and methods of making PHA using the same. However, only SEQ ID NO: 9 has been disclosed as encoding 3-hydroxyacyl-ACP thioesterase, and SEQ ID NO: 13 that encodes AlkK, which is acyl CoA synthetase. No other sequences encoding these activities have been disclosed, and no description has been provided that discloses the specific structural features that are required to confer the claimed activities.

“A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” In addition, “The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA’s relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention”. See *University of California v. Eli Lilly and Co.*, 119 F. 3d 1559; 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997).

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

Claims 1-3, 6, 13-15 and 20-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which

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it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to bacteria or plants that produce PHA that are transformed with a gene encoding an enzyme having the catalytic activity of 3-hydroxyacyl-ACP thioesterase so that medium chain length PHA accumulates, or transformed with both a gene encoding an enzyme having the catalytic activity of 3-hydroxyacyl-ACP thioesterase and a gene encoding acyl CoA synthetase and methods of making medium chain length PHA using the same. However, the specification fails to disclose any bacteria or plants transformed with one or both of these genes and producing medium chain length PHA. In addition, the specification only discloses SEQ ID NO: 9 as encoding 3-hydroxyacyl-ACP thioesterase, and SEQ ID NO: 13 that encodes AlkK, an acyl CoA synthetase. No other sequences encoding these activities have been disclosed, and no description has been provided that discloses the specific structural features that are required to confer the claimed activities.

Furthermore, 3-hydroxyacyl-ACP thioesterase is not known in the prior art and the specification fails to describe any features or means for identifying other sequences encoding the same activity. Note that sequence homology is not sufficient to predict function of encoded sequences. See the teachings of Doerks (TIG 14, no. 6: 248-250, June 1998), where it states that computer analysis of genome sequences is flawed, and "overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar functions" (the last sentence of the first paragraph of page 248). Doerks also teaches homologs that did not have the same catalytic activity because active site residues were not conserved (page 248, the first sentence of the last paragraph). In addition, Smith et al (Nature Biotechnology 15:1222-1223, November 1997) teach that "there are numerous cases in which

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proteins of very different functions are homologous" (page 1222, the first sentence of the last paragraph). Also, Brenner (TIG 15, 4:132-133, April 1999) discusses the problem of inferring function from homology, stating that "most homologs must have different molecular and cellular functions" (see the second full paragraph of the second column of page 132, for example). Furthermore, Borks (TIG 12, 10:425-427, October 1996) teaches numerous problems with the sequence databases that can result in the misinterpretation of sequence data.

More specifically, identification of related sequences that will encode enzymes having a particular activity is particularly problematic in the enzymes involved in modifying fatty acids, and cannot be determined merely by similarity of DNA or amino acid sequences. Van de Loo et al teach that sequences encoding fatty acid hydroxylase activity are highly similar to other sequences that do not encode a hydroxylase, but instead encode a fatty acyl desaturase (see the abstract, at least). In fact, Broun et al teach that a change in only four amino acids will convert a desaturase gene to a hydroxylase gene (see the abstract, at least). Thus, if sequences are identified only by similarity to other sequences that are known to encode a particular enzyme activity, one cannot conclude that these other sequences also encode enzymes having the same activity. In addition, De Luca teaches that modifying plant biosynthetic pathways by transforming plants with genes encoding enzymes involved in said pathway is highly unpredictable (see the paragraph bridging the columns on page 225N, for example), and that "on many occasions desired goals have been impossible to achieve" (see the last paragraph on page 228N). Therefore, both the identification of other genes encoding enzymes having these activities, and the modification of bacterial or plant PHA composition by transforming a plant with said gene or a portion of said gene are highly unpredictable.

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Thus, given the unpredictability of identifying sequences that exhibit a specific enzyme activity and modifying the PHA composition of a bacteria or plant; the lack of guidance in the specification for identifying and characterizing sequences that exhibit this activity; the lack of working examples of coding sequences that enhance medium chain PHA production, and the lack of working examples of similar sequences that encode proteins having the same activity; and the breadth of the claims, and use of said genes to produce medium chain PHA; it would require undue experimentation by one skilled in the art to make and use the invention as broadly claimed.

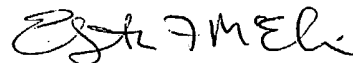
3. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Elizabeth F. McElwain, Ph.D.  
Primary Examiner  
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EFM